

PAYMENT OF RESEARCH SUBJECTS

Christine Grady, RN, PhD, FAAN
Head, Section on Human Subjects Research,
Department of Clinical Bioethics,
National Institutes of Health

Abstract: *Payment to research subjects is common but controversial. Guidance provided in the federal regulations and codes of ethics is minimal and subject to interpretation. Ethical concerns about paying subjects—undue inducement, preferentially attracting poorer populations, and the possibility of changing the nature of the investigator/subject relationship—are discussed. Three possible models for payment: market model, wage payment model, and reimbursement model, are highlighted, with the wage payment model, based on compensation for time and effort, recommended as the most useful and ethically appropriate. Areas for further research are outlined.*

Paying subjects to participate in clinical research is a concern to some who believe it may be an undue inducement. Many researchers believe that payment is acceptable as long as it is not an undue influence, but there is very little information available regarding how you determine when undue inducement is present.

Payment to research subjects is very common but there is a wide range of comfort with the practice (Table 1). Some investigators feel that it is a normal part of doing business. Others find it offensive to even consider paying research subjects. There is some guidance in the regulations and codes of ethics, but it is minimal and subject to interpretation. The Common Rule states only that "An investigator (must) obtain the legally effective informed consent of the subject or legally authorized representative . . . and shall seek consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." There are few data on payment practices, including how much researchers are paying, how

they are making these decisions, and any influence that payment might or might not have on people's decisions about participating in research.

FDA Information Sheets (1998) (Table 2) specifically address payment. According to these information sheets, the onus is on the IRB to review the amount and manner of payment being offered to subjects in a given study, and to make a judgment about whether the payment is appropriate or undue influence.

Ethical Considerations in Paying Research Subjects

Several reasons might justify offering payment to people participating in a research study. These are:

1. to avoid financial sacrifice on the part of participants,
2. as compensation for their time and effort, and
3. as an incentive to facilitate adequate and timely recruitment or completion of a study.

At the same time, ethical concerns in paying research subjects include concern about undue inducement, the possibility of preferentially attracting poorer populations, and the possibility of changing the nature of the investigator/subject relation-

ship. Since there are limited data on the demographic composition of research subjects, regardless of payment it is hard to know whether payment preferentially attracts poorer populations as participants. Researchers agree that they should avoid undue inducement, yet there is no consensus on how to determine what constitutes undue inducement. Decisions about payment to subjects are being left to investigators and IRBs, who have minimal guidance on how to make these decisions.

Three Payment Models for Research Subjects

In a paper we published in the New England Journal of Medicine in the summer of 1999, we proposed three possible models for payment: market model, wage payment model, and reimbursement model (Table 3). The market model emphasizes the idea of recruitment incentive, in this case, money. The more incentive needed to attract people to a study in a timely manner, the higher the pay. The result would be high payment for studies where it is hard to recruit subjects and lower payment for studies where it is easier to recruit subjects, competition between studies because researchers with more money could possibly recruit sub-

jects more easily, and use of strategies such as completion bonuses.

The wage payment model is based more on the notion of compensation for time and effort. The result would be a relatively low, standardized hourly wage, perhaps augmented by bonuses for uncomfortable procedures.

The reimbursement model is based on the notion that it should not cost people to participate in research. This could play out in two ways: reimbursement for expenses such as travel and meals or reimbursement for lost wages. Paying subjects for lost wages could open a Pandora's box by paying individuals differently depending on how much money they normally earn.

We recommended the wage payment model as the most useful and ethically appropriate way to think about payment to research subjects. Standardized and relatively moderate or low payments reduce the potential for undue inducement, provide some standardization across studies so as to minimize competition, and adhere to the principle of justice by paying individuals similar amounts for similar contributions.

Further research on payment to research subjects is needed, including research on:

- ☐ the impact of payment on recruitment,
- ☐ the effect of payment on informed consent and/or the demographics of subject populations,
- ☐ the effect of recruitment bonuses, referral fees, and so forth to physicians on recruitment, informed consent, and the demographics of subjects,
- ☐ which incentives people respond to in making decisions about participating in research, and
- ☐ whether subjects' cognitive, social, and physical status affect their response to incentives.

TABLE 1

Payment to Research Subjects

- A common practice
- A range of comfort with the practice of paying subjects
- Minimal guidance from regulations or codes of ethics exists
- Limited data on payment exist

TABLE 2

FDA Information Sheets (1998)

- It is not uncommon for subjects to be paid
- Payment is not considered a benefit but a recruitment incentive
- Financial incentives are often used when health benefits are remote or non-existent
- The amount and schedule of all payments should be presented to the IRB at the time of initial review
- The IRB should review the amount of payment and the method and timing of disbursement to assure that neither are coercive or present undue influence

TABLE 3

Three Models for Payment of Research Subjects

Market Model

- Research is somewhat risky, uncomfortable, and of no benefit to subjects; therefore, there is little reason for subjects to participate
- Payment represents an incentive to get subjects to participate
- Result: High payment and employment of strategies such as completion bonuses

Wage Payment Model

- Participation in research requires little skill but takes time, effort, and endurance of uncomfortable procedures
- Payment should be on a wage scale similar to other unskilled jobs
- Result: Pay a relatively low, standardized hourly wage, perhaps augmented by pay for particularly uncomfortable procedures

Reimbursement Model

- Research should not require financial sacrifice by subjects
- Payment should cover expenses in order to reduce the financial burden
- Result: Reimburse subjects for expenses only